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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,498	07/05/2001	Cynthia L. Bristow	F.11136	2583

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LIEBERMAN & NOWAK LLP
350 FIFTH AVE.
SUITE 7412
NEW YORK, NY 10118

EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	2

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
899498	BRISTOW
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-8 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The claims pending and under examination are 1-8.

The disclosure is objected to because of the following informalities: at page 6, line 12, as well as at page 10, line 10, it is believed that applicant intends --well-- in lieu of "will".

Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

OK by amend

The claims are utterly confusing because the preamble of claim 1 indicates one intends to test for HLE of the plasma membrane, while the body of claim 1, as well as claim 8, refer to "HLE receptors". It is deemed the former is correct.

attorney did this

Claim 1 is confusing in step D by reciting "monitoring said test sample for said immunocomplex", because step C has indicated that it is the "characteristic physical change" that can be monitored". It is suggested applicant recite step D as:

--D. Monitoring said characteristic physical change so as to detect HLE density of said plasma membranes.--

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Claim 1 is also incomplete because step D merely determines the "HLE density" without relating this density value to the "monitoring" recited in the preamble. It is suggested that applicant add a step such as:

--E. Relating said HLE density to said disease progression or phenomena.--

Claim 1 is also confusing in step C, fifth line thereof, in reciting "which when interacted with said HLE receptors". What does "which" describe --the preceding "immunoreagent" (fourth line) or the immediately proceeding "material"? The "material" (a label?) cannot itself "interact" with the HLE receptors; thus, it is improper for "which" to describe the "material".

Also in step C, line 6, it is unclear why applicant recites "in" instead of --on--, since step C, line 2, indicates that the "interaction with HLE receptors" occurs not "in" but, rather, "on said plasma membranes".

Claim 4 recites "pathological states" while claim 1 recites "pathologic phenomena"; consistency is required.

Claim 6 is improperly self-dependent.

In claim 6 "said reporter or indicator molecule" lacks antecedent basis.

Claim 6 appears to be incomplete at line 2. After "molecule" does applicant intend insertion of --is--? after "measured" does applicant intend insertion of --by--?

The Markush Group of claim 7 is utterly confusing because commas appear to set of alternative members from each other as well as descriptive phrases within each member. It is thus suggested that applicant recite the claim with an indentation of each member.

With regard to the above, note that claim 7 recites the member "a material discernible within the visible spectrum three times; only once is proper. The member or phrase (?) reciting "upon interaction with a substrate capable of forming a fluorescent material" is unclear. The last

member must be set off from the others by --or--. No new matter may be entered in the reformatting of claim 7.

In claim 8, lines 1-2, the recitation of "antigen or combination thereof" is unclear because applicant has described no "antigen" or any "combination" of antibody and antigen that specifically interacts with the HLE receptor. Since applicant has only taught an antibody as thus interacting one has no idea as to what is intended by "antigen or combination thereof".

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has given an inadequate description of an immunoreagent that is "specific for interaction with HLE receptors" (e.g. claim 1, part C).

Applicant's has adequately described immunoreagents (e.g. antibodies) that specifically interact with HLE associated with the plasma membrane. Applicant has, however, described no cell surface "receptor" for HLE and no immunoreagents that specifically interact with such a receptor".

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since applicant's disclosure has described no cell surface "receptor" for HLE and no

immunoreagents (e.g. antibodies) directed thereto, one would not know how to practice step C of claim 1 using such an unknown immunoreagent.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has failed to describe an immunoreagent that is an "antigen" or that is a "combination" of antibody and antigen that is specific for interaction with plasma membrane HLE receptors.

Applicant's disclosure has only described an antibody to HLE, not an antigen or any combination of antibody and antigen.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of an immunoreagent that is an antibody, does not reasonably provide enablement for the use of any immunoreagent that is an "antigen" or a "combination" of antibody and antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Since, as noted supra applicant has described no "antigen" or "combination" of antibody and antigen that specifically interacts with the plasma membrane associated HLE receptor, one would not even know how to practice a method using such unknown reagents.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was not in possession of the genus of diseases or pathologic phenomenon that "correlate with surface density of Human Leukocyte Elastase".

Applicant's disclosure, at the most, discloses AIDS and ARC as such pathologic phenomena. However, these two related conditions (ARC proceeds AIDS) are not representative of the genus. The mechanisms involved in the immune responses to various kinds of microbial organisms (e.g. viruses, bacterial, fungi, parasites) occur by means of widely divergent mechanisms --e.g. These can involve CD4+ lymphocytes of different subsets such as Th0, Th1 or Th2, can involve the actions of different types of effector cells --e.g. cytotoxic T-cells, macrophages, polymorphs, and can involve the participation of different kinds of chemokines and receptors therefore (e.g. the chemokines of The Th1 vs. The Th2 responses). Therefore a pattern of cell surface HLE expression associated with the progress or treatment of one type of infection cannot be predictably correlated with the progress or treatment of another type of infection. Also, the fact that HIV infects T-cells cautions against concluding that T-cell surface changes associated with HIV infection mimick those associated with all other infections. For like reasons, what might be correlated with one type of infection (such as that by HIV) cannot be predictably correlated with other pathologic states such as transplant rejection, autoimmunity, or cancer. Again within each of these latter categories what is correlated with one pathologic state

cannot be predictably correlated with another. For example, would the expression of cell surface HLE follow the same pattern in a cancer patient with prostatic carcinoma and in a cancer patient with a T-cell leukemia?

For the above reasons a mere description of changes of cell surface HLE expression associated with HIV infection cannot describe the genus of diseases or pathologic phenomena that correlate with the surface density of HLE.

The claims are allowable over the prior art of record. Bristiso is cited as showing aspects of the instant invention. This article post dates applicant's filing date.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

October 7, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644